**REMARKS**

In the Office Action mailed from the United States Patent and Trademark Office on April 4, 2008, claims 7-9 were rejected under 35 U.S.C. 112; claims 1-2 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,250,035 to Smith et al. ("Smith") in view of U.S. Patent Publication No. 2002/0123723 to Sorenson et al. ("Sorenson"); and claims 3-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. and Sorenson in further view of U.S. Patent Publication No. 2002/055715 to Young et al. ("Young").

M.P.E.P. § 2141 sets forth the *Graham* factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) In addition, M.P.E.P. §§ 2141 and 2142 set forth that "the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." (Citing *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007).)

The M.P.E.P. provides several examples of rationales that can support a rejection under 35 U.S.C. § 103, namely:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

(M.P.E.P. §§ 2141 & 2143, emphasis added.) As may be seen from the emphasized portions of the above potential rationales, each rationale is dependent on showing known elements from the prior art corresponding to the limitations of the claimed invention.

Therefore, for a rejection under Section 103 to stand, it must explicitly set forth 1) factual findings showing that each claim element was known in the art at the time of the invention, and 2) factual findings showing that one of ordinary skill in the art, at the time of the invention, would have found it obvious to modify or combine the teachings to arrive at the claimed invention. (See, for example, the enumerated required articulations set forth in M.P.E.P. § 2143 for each lettered rationale.)

Note that M.P.E.P. sections 2141 and 2142 set forth that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious; rejections on obviousness cannot be sustained by mere conclusory statements. (Citing *KSR*, 82 USPQ2d at 1396 & *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).) Thus, a rejection under Section 103 cannot stand if it contains a mere statement that the claimed invention would have been obvious without explicitly enumerating the necessary factual findings.

Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. In particular independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having at least three fenestrations longitudinally disposed and **isolated on a distal end** of said hollow needle.

The peripheral nerve block needle of the present application is designed such that fenestrations are located proximate a distal end of a needle. Claims 1, 5 and 7; Specification, page 7, lines 12-22. The importance of localizing the fenestrations near the distal end of the needle is elucidated in a non-limiting example found on page 8 of the specification, which indicates that "fenestrations are preferably located within one or two millimeters, and most preferably within 0.17 inches of each other for this purpose," wherein said purpose is to "deliver drug approximate to the lower extremity nerves which comprise only a few millimeters in width, for example a discrete compartment of only a few millimeters is located between the semitendinosis muscle 32 and bicep femoris muscle 34. This facial compartment 30 houses the sciatic nerve 36, one of two major lower extremity nerves, fenestrations 20 are space at relatively small intervals along the needle 12 in order to maximize an even distribution of local anesthetic to any particular facial compartment 30, including particularly male compartments such as the housing of the sciatic nerve 36." Specification, pg. 8, lns. 7-17.

The pending action relies on Sorenson to teach modifying Smith's needle to include multiple apertures "because doing so provides a wider distribution of fluid than with a single opening (Sorenseon et al, Paragraph [0033])." Office Action, page 4. In accord with the Examiner's observations, Sorenson teaches an apparatus for specific interstitialor subcutaneous **diffusion** and **dispersion** of medication along the tubular element's length. Sorenson, abstract. Accordingly, Sorenson discloses a method of administering medicine along the entire length of the needle inserted into a patient. Use of Sorenson's needle and its release of drugs along the entire length of the needle produces a dangerous situation if utilized to administer drugs to block peripheral nerves as claimed by the present application.

Independent claims 1, 5 and 7, contain a limitation requiring that the fenestrations are isolated on a distal end of the fenestrated needle. This is very different than the plurality of perforations disclosed in Sorenson that release anesthetics along its entire length so that it uniformly disperses medication to a treatment zone. Sorenson, paragraph 33. Sorenson specifically differentiates itself from the "point-source" fluid introduction of other devices. In

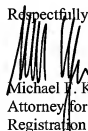
contrast to the broad, uniform release strategy of Sorenson, the present invention focuses on precisely placing its injections in order to avoid intravascular injection and/or inadvertent penetration of a nerve. Specification, page 3, lines 20-22. Because the space in the facial plain is very small and located proximate a nerve exact dispersion of medicine is required. Thus, it would be dangerous to apply the teachings of Sorenson to the present invention, as application of Sorenson's invention would likely send anesthetic outside the boundaries of the well defined facial compartments in which Applicant directs the anesthetic. Because the combination of art does not teach every limitation of the claimed invention, Applicant respectfully requests that the Examiner withdraw his Section 103 rejection.

**CONCLUSION**

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 7 day of July, 2008.

Respectfully submitted,



Michael J. Krieger
Attorney for Applicant
Registration No. 35,232

KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111
(801) 328-3600

JRM/brc
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